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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,936	09/23/2003	Michele Sanicola-Nadel	13751-045003	3298

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1643

MAIL DATE	DELIVERY MODE
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10/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/668,936

Applicant(s)

SANICOLA-NADEL ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3-5 and 11-13 is/are allowed.
- 6) ☒ Claim(s) 1,2 and 6-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-13 are pending.

Claims 1-13 are examined on the merits.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The rejection of claims 1, 2 and 6-10 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. The rejection of claims 1, 2 and 6-10 under 35 U.S.C. 102(e) as being anticipated by United States Patent Application Publication number 2004/0235714 A1 (effective filing date April 22, 1996). The publication discloses sequences 42 and 38, which share at least 92% and 99% sequence homology with Applicants' SEQ ID NO: 17 and 21, respectively, is withdrawn in light of Applicants' arguments denoting the publication's priority documents do not disclose sequences 42 and 38.

6. The rejection of claims 1, 2 and 6-10 under 35 U.S.C. 102(e) as being anticipated by United States Patent number 7,138,251 B1 (effective filing date April 22, 1996). The patent discloses sequences 42 and 38, which share at least 92% and 99% sequence homology with Applicants' SEQ ID NO: 17 and 21, respectively, is withdrawn in light of Applicants' arguments denoting the publication's priority documents do not disclose sequences 42 and 38.

Maintained Grounds of Rejection

Claim Rejections - 35 USC § 112

8. The rejection of claims 1, 2 and 6-10 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

Applicants continue to assert the disclosed RetL3 proteins constitute a functional polypeptide that interacts with the receptor tyrosine kinase Ret and the skilled person would readily expect that the claimed polypeptides would likely be amenable to change without eliminating biological activity, see paragraph bridging pages 2 and 3 of the Remarks submitted July 16, 2007. These points of view and arguments have been carefully considered, but found unpersuasive. These points of view and arguments have been carefully considered, but found unpersuasive.

Applicants continue not to be in possession of all proteins that have reduced sequence homology to wild type proteins, SEQ ID NO: 17 and SEQ ID NO: 21. The written description in this case only sets forth Ret ligands as listed in claims 3-5 and 11-13.

Applicants' arguments and specification do not note which amino acids are critical to the disclosed function; which amino acids can be changed without destroying the conformation of the polypeptides thus not allowing trigger dimerization of the receptor protein Ret and autophosphorylation of a tyrosine kinase domain of the receptor protein Ret; and what are the domains within SEQ ID NO: 17 and SEQ ID NO: 21 that must be maintained to facilitate the claimed functions. The nexus between the structure and the

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function of the claimed proteins with reduced sequence homology has not been set forth. When there is substantial variation with the genus, such as in the instant case one must describe a sufficient variety of species to reflect the variation within the genus, see 1242 Official Gazette 174, January 30, 2001. A genus that embraces widely variant species cannot be achieved by disclosing only one species with the genus. Applicants' claims embody a host of polypeptides, which has not been provided within the specification. Applicants seem to only be in possession of SEQ ID NO: 17 and 21. As noted in the first action on the merits (FAOM) mailed September 27, 2006 adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The polypeptide itself is required known to definitively not eliminate biological activity. For the reasons of record the rejection is maintained.

Allowable Subject Matter

9. Claims 3-5 and 11-13 are allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone

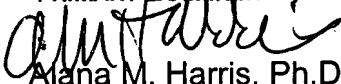
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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER



Alana M. Harris, Ph.D.

01 October 2007